JUN 1 3 2001

K 002695

510 (k) SUMMARY

The enclosed is a Summary of our 510(k) Submission of the Memodyn Staples which is substantially equivalent to current and legally marketed devices.

TRADE NAME:
Memodyn Staples

CLASSIFICATION NAME:
Staple, Bone fixation, Product Code: 87 JDR

EQUIVALENCE:
The Memodyn Staples are substantially equivalent to current and legally marketed devices. Examples are enclosed and include DePuy, Inc. (K 964226) and Surgical Implants, Inc. (K 991962). Each staple is manufactured the same and its indication is the same. The one has an oval shape on the bridge and the other has an identical "S" shape.

DESCRIPTION:
The Memodyn Staple is a memory staple, that comes in different sizes, used for bone fixation on osteotomies, arthrodesis and fractures.

INTENDED USE:
The Memodyn staples are for adjunctive bone fixation of osteotomies, arthrodesis and fractures of small bones of the foot, ankle and hand.

CHARACTERISTICS:
There are no significantly technological characteristics of the Memodyn Staples compared to existing, legally marketed devices of which examples are listed above (Equivalence Sections).

Summary Prepared by:

Al E. Austin
Manager/Sales and Quality Assurance
Austin & Associates, Inc./TELOS Medical

Summary Prepared On:
08-25-00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2001

Telos Medical Equipment
c/o Mr. Al E. Austin
Austin & Associates, Inc.
1109 Sturbridge Road
Fallston, Maryland 21047

Re: K002695
Trade Name: Memodyn Staple
Regulation Number: 888.3030
Regulatory Class: II
Product Code: JDR
Dated: March 23, 2000
Received: March 28, 2000

Dear Mr. Austin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002695

Device Name: Memodyn Staple

Indications For Use:

The Memodyn staples are for adjunctive bone fixation of osteotomies, arthrodesis and fractures of small bones of the foot, ankle and hand.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DMitchell MS for CAW

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002695

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

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(Optional Format 1-2-96)